



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0232]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealer's Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0021. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealer's Certificate

OMB Control Number 0910-0021--Revision

Under section 243 of the Public Health Service Act (42 U.S.C. 243) FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations, and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, we participate with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP). NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors.

Each NSSP-participating State and foreign nation monitors its molluscan shellfish processors and for purposes of interstate or international commerce issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate." We use this information to publish the "Interstate Certified Shellfish Shippers List," a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If we did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate and international commerce, and its effectiveness would be nullified.

In the *Federal Register* of March 9, 2018 (83 FR 10487), we published a notice seeking comment on a proposed determination that the European Union's (EU's) system of food safety control measures for raw bivalve molluscan shellfish intended for export into the United States, as adopted and implemented in Spain and the Netherlands, provides at least the same level of sanitary protection as the United States equivalent. If finalized, such a determination would permit the importation of shellfish harvested from certain European production areas and processed by European establishments that have been listed by FDA on the Interstate Certified Shellfish Shippers List.

The March 9, 2018, notice also described the European Commission's (EC's) determination that the United States' system is equivalent to its own, and as a result of that determination, its stated intent to accept shellfish from certain growing areas in the United States. On November 6, 2018, the EC published Commission Implementing Decision (EU) 2018/1668 which added the United States (MA and WA only) to the list of Third Countries from which molluscan shellfish imports are permitted. Shellfish harvested from growing areas with an Approved classification in those states are eligible for export to the EU.

As part of the equivalence determination, the EC identified the need for FDA to provide documentation collected from NSSP-participating shellfish control authorities seeking recognition under the EC's equivalence determination. This documentation includes:

- A list of growing areas with an Approved classification,
- The most recent sanitary survey for each growing area with an Approved classification, and
- The most recent inspection report for each firm seeking to export shellfish to the EU.

For NSSP-Participants that do not produce live/raw shellfish required documentation is limited to the most recent Plant and Shipping Element Program Evaluation Report and the most recent inspection report for each shellfish processing firm to be listed for export to the EU.

In the *Federal Register* of June 8, 2018 (83 FR 26699), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of Interstate Shellfish Dealer's Certificate	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of NSSP Compliance Documentation	N/A	13	1	13	0.25 (15 minutes)	3.25
Total						231.25

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates (Form FDA 3038) annually, or an average of 57 responses per respondent. We estimate that it takes a respondent an average of 6 minutes or 0.1 hour to complete each form for a total burden of 228 hours (2,280 submissions \times 0.10 hours). This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

In order to gain equivalence recognition by the EC, we estimate that respondents will make a one-time submission of documents demonstrating NSSP compliance. We estimate that 13 respondents will each submit 1 response, for a total of 13 responses. We estimate that each response will take 15 minutes, or 0.25 hour, for an annual total of 3.25 hours (13 responses \times 0.25 hour).

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-08174 Filed: 4/23/2019 8:45 am; Publication Date: 4/24/2019]